Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054056	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/012557	International filing date (*day/month/year*) 11 November 2003 (11.11.2003)	Priority date (*day/month/year*) 13 November 2002 (13.11.2002)
International Patent Classification (IPC) or national classification and IPC A23L 1/30		
Applicant BASF AKTIENGESELLSCHAFT		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03 June 2004 (03.06.2004)	18 April 2005 (18.04.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/012557

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☐ the international application as originally filed.

☒ the description, pages 1-12, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-16, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☐ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRE[redacted]NARY EXAMINATION REPORT

International application No.
PCT/[redacted] 03/12557

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	12-14	YES
	Claims	1-11, 15-16	NO
Inventive step (IS)	Claims		YES
	Claims	1-16	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: US-A1-2002/048 606 (ZAWISTOWSKI JERZY) 25 April 2002 (2002-04-25)

D2: WO-A-01/00046 (COGNIS DEUTSCHLAND GMBH; SCHROEDER CHRISTINE (DE); DOLHAINE HANS (DE)) 4 January 2001 (2001-01-04)

D3: US-B1-6 391 370 (GAONKAR ANILKUMAR G ET AL) 21 May 2002 (2002-05-21)

D4: FR-A-2 817 478 (OREAL) 7 June 2002 (2002-06-07)

D5: SJOSTROM B ET AL: "A METHOD FOR THE PREPARATION OF SUBMICRON PARTICLES OF SPARINGLY WATER-SOLUBLE DRUGS BY PRECIPITATION IN OIL-IN-WATER EMULSIONS. II: INFLUENCE OF THE EMULSIFIER, THE SOLVENT, AND THE DRUG SUBSTANCE" JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN PHARMACEUTICAL ASSOCIATION. WASHINGTON, US, Vol. 82, No. 6, 1 June 1993 (1993-06-01), pages 584-589, XP000367863 ISSN: 0022-3549

D6: WO-A-02/17892 (NOVARTIS NUTRITION AG; AURIOU NICOLAS (CH)) 7 March 2002 (2002-03-07)

D7: US-B1-6 576 285 (BADER PRIMO ET AL) 10 June 2003 (2003-06-10)

D8: US-A-4 522 743 (DITTER WALTER ET AL) 11 June 1985 (1985-06-11)

D9: WO-A-01/32036 (MENON VINOD P; MONSANTO CO (US); KINLEN PATRICK J (US); PRIAKITIKULR) 10 May 2001 (2001-05-10).

The priority of the present application is currently assumed to be valid and therefore document D7 is not taken into account.

The subject matter of claim 1 is not novel (PCT Article 33(2)), because documents D1, D2 and D6 already disclose equivalent phytosterol formulations in powder form.

D1 (see, e.g., paragraph 40, lines 3 to 5) discloses a phytosterol in powder form with a preferred particle size of 100 micrometres.

D2 (claims 1, 2, 4, 5) discloses nanoscale phytosterols with particle diameters of 10 to 300 nm. The solvent is evaporated during production. Nanoparticles - which can also be termed a powder, even without explicit mention - are produced.

D6 (claim 1 and page 7, lines 4 to 6) discloses phytosterol formulations in powder form. The particle size of the micelles to be dried is preferably 10 to 100 micrometres.

The subject matter of claim 10 is not novel, because document D2 already discloses an equivalent method.

In D2 (see the example on page 6), the sterols are dissolved in liquid CO_2 (organic solvent) and sprayed into an aqueous dispersion of the protective colloid (that is, mixed with a colloid-disperse aqueous solution of the protective colloid). Disperse nanoparticles with a size of 0.055 to 0.15 micrometres are produced. The fluid medium evaporated - the dispersion was therefore freed from the solvent. That step can also be considered as drying.

The subject matter of claim 12 is novel, because no document clearly discloses an equivalent method.

In D1 (paragraphs 33 and 35), phytosterol is, for example, dispersed or suspended in aqueous solution and ground with a colloid mill. Protective colloids and drying are not explicitly mentioned in this connection.

In D3 (abstract, example 1), phytosterols in aqueous dispersion are ground together with an emulsifier (e.g., polysorbate, which might also be termed a protective colloid). There is no drying step, however. Particles with a size of 10 micrometres are produced, but no powder.

In D6 (claim 1, page 7, lines 4 to 6, page 8, last paragraph to page 9, first paragraph), phytosterols in aqueous solution are mixed with starch and other additives to form an emulsion containing micelles with a size of 1 to 400 micrometres, preferably 10 to 100 micrometres, which is then dried. The methods used for the preparation of the emulsion are listed on page 8 (shear mixing, vortexing, sonication, microfluidising, French press). Those methods cannot necessarily be termed "grinding", even though high shearing forces have to be exerted in all cases.

However, the subject matter of claim 12 is not inventive (PCT Article 33(3)).

The problem addressed by the invention (description, page 2, lines 7 to 16) is that of providing phytosterol-containing formulations which can be incorporated into both aqueous and oily preparations. This problem is solved by means of the particle size.

D3 (see column 3, lines 11 to 27) can be considered to be the closest prior art. Formulations are prepared which may be both aqueous and oily dispersions. The method of preparation differs only in that there is no final drying step and therefore no powder is produced. Drying, however,

is a conventional method step which is not essential for the solution to the problem. It merely facilitates handling of the end product. Consequently, an inventive step cannot be substantiated.

Claims 15 and 16 are not novel. D1, D2 and D6 disclose equivalent uses and means and preparations.